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INVENTOR(S)					
Given Name (first and middle [if any])		Family Name or Surname		Residence (City and either State or Foreign Country)	
Joaquin Andres		HOFFER		Anmore, British Columbia CANADA	
<input type="checkbox"/> Additional inventors are being named on the ___ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (280 characters max)					
ELECTRICAL STIMULATION METHOD FOR TREATING PHANTOM LIMB PAIN AND OR PROVIDING SENSORY FEEDBACK ARISING FROM A PROSTHETIC LIMB					
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Respectfully submitted,

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36,412

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**ELECTRICAL STIMULATION METHOD FOR TREATING
PHANTOM LIMB PAIN AND/OR FOR PROVIDING SENSORY
FEEDBACK ARISING FROM A PROSTHETIC LIMB**

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B.C. Canada V3H 3C8

Technical Field

This invention relates to methods and apparatus for relieving phantom limb pain in amputees. The methods use implantable interfaces to bodily tissues in amputees to provide sensory feedback from a prosthetic limb and/or to treat phantom limb pain. Preferred embodiments of the invention make use of multi-channel interface structures. The interface structures may be implanted to permit stimulation of internal body tissues, such as nerves. The interfaces may be provided in the form of nerve cuffs. The interfaces may provide electrical, optical and/or chemical connections to selected bodily tissues.

Background

Limb amputations cause 3 major types of dysfunction. Two of these occur immediately and are direct consequences of the amputation:

1. loss of motor function distal to the amputation level, and

2. loss of sensory feedback from the missing limb distal to the amputation level.

A third dysfunctional consequence is an indirect result of amputation:

3. "phantom limb" sensations and in particular phantom limb pain.

This invention provides methods for replacing lost sensory function from a missing limb and also describes methods for treating "phantom limb" sensations and in particular phantom limb pain.

The causes for the often very vivid and disturbing phantom limb sensations reported by a majority of limb amputees are not completely understood, but it is believed that several processes are responsible. Subsequent to loss of their normal peripheral sensory nerve input, neurons in regions of the cerebral cortex and in particular in the primary sensory cortex associated with the amputated limb can greatly increase their receptivity to synaptic inputs arising from the sensory nerves that remain in the limb stump but are now disconnected from their sensory end-organs. Cortical neurons can also become receptive to sensory input arising from other regions of the body, in particular from regions that normally project to areas of cortex adjacent to the cortical areas originally dedicated to the amputated limb or body parts. This cortical response process, described as "cortical plasticity" (Srinivasan et al, 1991), can be manifested as early as 2 hours after experimental digit nerve amputation in animal models (Merzenich, Kaas) and continues to develop for many weeks and months if peripheral nerves

remain transected and cannot reestablish contact with their original target organs. It is believed that this greatly increased responsiveness of cortical neurons to inappropriate sensory inputs is at least partly responsible for "phantom limb" sensations. Phantom limb sensations are interpreted to arise from the missing limb or digits, even though the sensations may be triggered by sensory receptors from other body regions or by random activity in the disconnected sensory endings within the amputated limb stump.

The phantom limb sensations may or may not include pain components. When pain is present, it is sometimes of such intensity that it becomes unbearable or extremely disabling to the amputee. One possible mechanism to account for the occurrence of phantom limb pain is that amputation eliminates or greatly disrupts the normal flow of sensory information arising from other modalities of sensory receptors (e.g., low-threshold cutaneous or muscle receptors) carried by larger diameter, myelinated axons. These sensory axons normally convey non-painful information of proprioceptive and cutaneous origin such as touch, pressure, temperature, muscle length, tendon force and joint position information. In one major theory of synaptic connectivity in the central nervous system proposed by Wall and Melzack, synaptic input from large myelinated sensory fibers normally converges on interneurons that mediate pain pathway information and tend to inhibit the transmission of pain sensations that are conducted by smaller diameter, unmyelinated sensory nerve fibers. In the absence of proprioceptive and cutaneous information that could inhibit the

transmission of pain, the pain pathways are open. The sensations of pain that reach the cortex are interpreted to arise from the missing limb or digits (thus the term "phantom limb" pain), even though the sensations may be triggered by sensory receptors from other body regions, or by random activity in pain afferents in the nerve stumps in the amputated limb or digits.

An important landmark in the pain scientific literature is the work by Wall and Melzack, who in the 1960's proposed the "Gate Control Theory" of pain whereby activity in large diameter touch A β nerve fibers were hypothesized to reduce the central transmission of pain activity information carried to the spinal cord by smaller A δ and C fibers. Although this hypothesis remains controversial, it has brought a focus on the complex interactions that can exist among parallel sensory inputs of different modalities, and on the various central and peripheral factors that can contribute to the central perception of pain. It is now generally accepted that the balance of activity in large and small diameter sensory nerve fibers is important in pain transmission in the spinal cord and brain centers.

With respect to the fate of nerve fibers in amputated limbs, it is known that all nerve fibers in a severed nerve may atrophy to some extent in the sense that the fiber diameters are reduced, but the nerve cells generally remain viable in the sense that they continue to conduct electrical impulses and retain their basic synaptic connectivity patterns. It is also known that sensory fibers atrophy relatively more

than motor fibers (Hoffer et al., 1979) and, furthermore, large-diameter sensory fibers typically atrophy more than small-diameter sensory fibers, and similarly large-diameter motor fibers typically atrophy more than small-diameter motor fibers. For hind limb nerves of cats that were cut and ligated over a period of 300 days, Milner et al. (1981) found that large sensory fibers had a 60% decrease in conduction velocity (CV); small sensory fibers had about a 45% decrease in CV; large motor fibers had a 40% decrease in CV; and small motor fibers had about a 20% decrease in CV. Thus, in amputated nerves, "large" and "small" nerve fibers will gradually become closer in their diameters and consequently closer in their thresholds for electrical stimulation.

Description of Prior Art.

Various pharmacological approaches have been proposed for treating phantom limb pain. Analgesics have generally not worked against this kind of pain. Antidepressant medications can reduce the sensation of pain, but have serious side effects that have limited their applicability. There are currently no approved drugs that are recognized to treat phantom limb pain safely and effectively without unwanted side effects. Another approach, blockade or removal of the sympathetic supply to the stump, can provide temporary reduction of phantom pain but the effects depend on how soon after amputation the procedure is done, and may not be long-lasting (Livingston, 1945).

Electrical stimulation of nervous structures can be effective in providing relief of pain in certain types of peripheral pain. Two main

approaches used to date are transcutaneous electrical nerve stimulation ("TENS") and dorsal column stimulation (DCS) in the spinal cord. It is likely that the mode of action of these therapies involves the stimulation of large diameter sensory fibers in limb nerves (TENS) or in the spinal cord (DCS) and reduce the transmission of pain in central pathways described by the Gate Control Theory. However, application of these electrical stimulation techniques has had only modest success for treatment of phantom limb pain in amputees. It is likely that TENS ceases to be effective as the sensory fibers in amputated nerves become gradually thinner and therefore their electrical thresholds will gradually rise, to the point that they can no longer be recruited effectively with TENS.

There is limited, but encouraging, published evidence that it is possible to selectively stimulate large-diameter sensory fibers in severed nerves of amputees using a nerve cuff to provide electrical stimulation, and elicit touch sensations without causing any concomitant pain sensations. Stein et al (1980) showed that it is possible to elicit sensations that the amputee interpreted to arise from an amputated limb, by electrically stimulating sensory axons using a nerve cuff implanted around a ligated peripheral nerve inside the forearm stump of a below-elbow arm amputee. Even though the arm had been amputated over 30 years earlier, the amputee subject was able to clearly sense the stimulation, which he reported as a non-noxious tingling sensation arising from the ulnar aspect of his phantom limb, specifically from the ring and small fingers which is the sensory

field that is normally innervated by the ulnar nerve. Thus, at least some sensory nerve axons survived over 30 years in a ligated nerve and retained their central connections. The amputee was able to subjectively discriminate frequencies of stimulation ranging from single pulses to steady rates up to 10-20 Hz. For frequencies greater than 20 Hz the sensations were reported as either fused or absent, indicating that the nerve fibers could have been fatigued by high-frequency stimulation in this patient.

Summary of Invention

Activity in larger diameter sensory fibers can help suppress the central perception of pain information carried by smaller diameter fibers and, as a corollary, when there is an absence of activity that would naturally occur in large diameter sensory fibers, such as in touch receptor afferents that have been disconnected from their peripheral sensory organs, there is a greater chance for pain sensations to reach consciousness. According to this invention, this condition, when it occurs in amputees, for example, may be reversed by selective electrical stimulation of the larger sensory fibers to so restore sensory traffic in these fibers, thus restoring a more normal balance of activity in large and small diameter fibers which will and counterbalance again the excessive flow of pain information in central pathways.

One aspect of this invention provides an implanted electrical stimulation system with an electrode or electrodes located in, around or near the severed peripheral nerve stumps that remain inside the

proximal stump of an amputated limb. Appropriately chosen electrical stimulation parameters can accomplish the following desirable purposes: 1) provide sensory feedback about parameters of a prosthetic limb, such as touch, pressure, force, slip, joint position or temperature information, and/or 2) provide an effective method of treatment of phantom limb pain. Alternatively, one or more catheters can provide selective delivery of pharmacological agents to the nerve stumps for the treatment of pain. The invention has particular application to multi-channel interface structures, which may be implanted to permit stimulation of multiple sites or sensory modalities of internal body tissues, such as nerves, together with selective infusion of chemical substances. The interfaces may be provided in the form of nerve cuffs. The interfaces may provide electrical, optical and/or chemical connections to selected bodily tissues.

Preferred embodiments of the invention increase the effectiveness of selective recruitment with electrical stimulation of large sensory nerve fibers in severed nerve stumps in amputated limbs by providing electrodes which are implanted inside the amputated limb, directly on or very close to the nerve stumps. This is because the differential atrophy of nerve fibers of different diameters, that causes the thresholds for electrical stimulation of large and small sensory fibers to gradually move closer together. Placing the stimulating electrodes closer to the nerve provides an improved means for selectively stimulating the large fibers even after they have atrophied as a consequence of the nerve amputation.

Most preferably the electrodes are cuff electrodes. Cuff electrodes are considered to be more efficient than other types of electrodes for providing the desired stimulation. Multichannel electrodes are also more efficient for selectively recruiting desired sensory nerve modalities with electrical stimulation. Multi-chambered nerve cuffs are considered to be the most efficient design for providing multichannel stimulation.

Another aspect of this invention provides a method of application of non-noxious electrical stimulation of larger, lower-threshold myelinated sensory axons in severed nerve stumps, which may serve to disfacilitate or inhibit the transmission of pain sensations in central pathways. This mode of stimulation may also act to arrest or reduce the evolution of synaptic changes that are believed to occur in the sensory cortex after limb amputation that may be responsible for "phantom limb" sensations, and in particular phantom limb pain sensations.

DESCRIPTION OF DRAWINGS

In drawings which illustrate example embodiments of the invention, Figure 1 is a schematic view of a stump and prosthesis equipped with apparatus for practising the methods of the invention; and,

Figures 2A and 2B are perspective and cross sectional views of a multi-channel nerve-cuff surrounding a nerve stump.

LIST OF REFERENCE NUMERALS USED IN THE DRAWINGS.

1. Ligated end of severed limb nerve that had innervated that forearm, hand and digits.
2. Amputated limb stump.
3. Nerve cuff containing stimulation electrodes.
4. Flexible cable leading from electrodes to implanted electronics.
5. Implanted electronic circuitry for stimulation and telemetric signal transmission.
6. Internal receiving antenna.
7. Socket of prosthetic limb containing electric motors and feedback control circuitry.
8. Electromechanical prosthetic hand.
9. A-D Various electromechanical sensors placed in the hand and wrist of prosthesis to monitor parameters such as touch, pressure, force, slip, joint position or temperature.
10. External transmission antenna (located close to Internal receiving antenna 6).
11. Cable connecting external antenna to external control unit.
12. External control unit that monitors voluntary command signals 17 generated by amputee, as well as sensory signals 15 transmitted from sensors in prosthesis 9 via antenna 13 of telemetry unit 14 and provides telemetric output control signals 16 that control the motors in prosthetic limb (not shown).
13. Antenna 13 of telemetry unit 14 that transmit sensory signals from sensors in prosthesis 9.

14. Electronic circuitry for transduction of sensory signals from sensors in prosthesis 9 and telemetric signal transmission to external control unit 12.
15. Sensory signals transmitted from sensors in prosthesis 9 via antenna 13 of telemetry unit 14.
16. Telemetric output control signals 16 produced by external control unit 12 that control the motors (not shown) in prosthetic limb 7 and hand 8.
17. Voluntary command signals generated by amputee to control position and movement of the prosthetic limb.

Figures 2A, 2B.

21. Multi-channel, multi-chambered nerve cuff containing stimulation electrodes and catheters, placed around amputated nerve in a location proximal to nerve stump 1.
22. Internal ridges that form chambers inside cuff.
23. Chamber
24. Stimulation electrodes placed inside chambers for selective stimulation of parts of nerve
25. Catheters placed inside chambers for selective treatment of parts of nerve
26. Limb nerve placed inside nerve cuff.
27. Perineurium.
28. Nerve fascicles.
29. Nerve axons.

30. Interdigitated tubular members used for opening and closing cuff
31. Cuff closing member introduced through the interdigitated tubular members

5 **DESCRIPTION**

10 As shown in Fig. 1, an external control unit 12 monitors the sensory information flow arriving from sensors in the prosthetic limb 9 and provides sensory feedback information to the amputee by way of the pair of communicating antennae 10 and 6 in order to provide selective electrical stimulation of sensory nerve fibers using a nerve cuff placed around a severed limb nerve 2 that had innervated that forearm, hand and digits before the amputation. The external control unit 12 also monitors the voluntary command signals 17 generated by the amputee together with the sensory information flow arriving from sensors in the prosthetic limb 9 and controls the action of the motors (not shown) placed in the prosthetic limb and hand that control the position and movement of the prosthetic limb joints and the digits in the prosthetic hand 8.

20 The external control unit 12 can also provide patterns of electrical stimulation to nerve 2 that may not depend on the flow of information of sensors 9 in the prosthetic limb 7,8, but are designed to treat phantom limb pain according to the teachings of this invention.

25 Figure 2A, 2B show a preferred embodiment of a multi-channel, multi-chambered, laser-fabricated nerve stimulation cuff placed around a

severed nerve in an amputated limb. As per teachings in prior art, electrodes 24 and catheters 25 are placed within individual chambers 23 separated by ridges 22 that increase the selectivity of electrical stimulation and drug action directed to only some parts of the nerve contained within the cuff.

The preferred embodiment of the invention provides a closure 30 comprising interdigitating tubular members 30 as described in Kallesøe et al., U.S. patent No. 5,487,756, which is incorporated herein by reference. Closure 30 may be fabricated from continuous tubes affixed along either side of cuff opening. Tubes 30 are preferably silicone tubes which may be affixed with a biocompatible silicone adhesive.

In a preferred embodiment the various apertures for electrodes 24 and catheters 25 required in the interface are cut in the cuff wall. A laser cutter may be used to cut apertures for electrodes 24 and catheters 25. The laser cutter can also cut tubes 30 to form an interdigitating set of tubular members 30 affixed along each edge of the cuff.

The preferred embodiment of the invention provides a multichannel nerve cuff 21 having a closure 22 comprising interdigitating tubular members 23 as described in Kallesøe et al., U.S. patent No. 5,487,756, which is incorporated herein by reference. Closure 22 may be fabricated from continuous tubes 60 affixed along either side of the nerve cuff. Tubes 60 are preferably silicone tubes which may be affixed with a

biocompatible silicone adhesive such as the adhesive mentioned above.

Description of preferred embodiments and methods of stimulation:
to treat phantom limb pain

5 Stimulation preferably will be applied for 24 hours per day.

If a feedback system from sensors in the prosthetic limb is also used, stimulation will preferably be applied during the night or during those periods when the prosthetic limb is not also in use.

If a single-channel system is used, electrodes could be of many types; for example wire electrodes placed near, on, or inside nerves, or inside a nerve cuff for increased efficiency.

For single-channel stimulation, examples of preferred stimulation parameters are:

- Use trains of brief duration stimuli, preferably 10-1000 μ s in duration, preferably negative-going if monophasic, preferably negative/positive if biphasic. Biphasic stimulation is preferred in order to balance the net flow of charge. If biphasic, the duration of the second (positive) stimulus pulse should 2-10 times longer than the duration of the first (negative) stimulus pulse and the amplitude should be 2-10 times lower so that the duration-amplitude product is the same for the two pulses.

- 5
- Voltage, current or charge density per stimulation impulse is preferably in the range of 1-10 times the threshold value for first recruitment of large-diameter sensory fibers, in order to not recruit pain fibers of smaller diameter and higher threshold. Threshold can be determined by the lowest level of stimulation that is detected by the amputee as causing a sensation of cutaneous or proprioceptive modality. Another way to determine the maximum stimulation to be used is by having the amputee report the highest level of stimulation that does not cause a noxious or painful sensation and keeping the stimulation safely below the threshold level for pain.

- 10
15
20
- Provide the stimulation in trains in the range or up to the maximum frequency that is perceived as non-fused tetani by the amputee, which could be as low as 10-20 Hz or as high as 300 Hz (300 impulses per second). The stimulation can be provided as a constant-frequency train, as regular bursts of constant frequency stimuli, as random bursts, as bursts of gradually increasing/decreasing frequency, or in many other patterns that are determined in part by the reported sensations elicited in the amputee and by the expressed preference of the amputee.

For multi-channel systems, use essentially similar patterns but these can be provided independently to each channel, in such a way that

all the stimulation parameters may be different and independently controlled for each channel.

5 Electrical stimulation to treat phantom limb pain is delivered preferably by a totally implanted unit that is either battery powered or telemetry-driven and can be externally programmed to optimize stimulation patterns, and its operation can be controlled by the amputee.

Where the goal is to provide sensory feedback arising from the prosthetic limb: Stimulation preferably will be applied continuously during those periods when the prosthetic limb is connected and in use.

If a single-channel system is used, electrodes could be of many types; for example wire electrodes placed near, on, or inside nerves, or inside a nerve cuff for increased efficiency.

For single-channel stimulation, examples of preferred stimulation parameters are:

- 20 • Use trains of brief duration stimuli, preferably 10-1000 μ s in duration, preferably negative-going if monophasic, preferably negative/positive if biphasic. Biphasic stimulation is preferred in order to balance the net flow of charge. If biphasic, the duration of

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5

- Voltage, current or charge density per stimulation impulse in the range of 1-10 times the threshold value for first recruitment of large-diameter sensory fibers, in order to not recruit pain fibers of smaller diameter and higher threshold. Threshold can be determined by the lowest level of stimulation that is detected by the amputee as causing a sensation of cutaneous or proprioceptive modality. Another way to determine the maximum stimulation to be used is by having the amputee report the highest level of stimulation that does not cause a noxious or painful sensation and keeping the stimulation safely below the threshold level for pain.
- Provide the stimulation in trains in the range or up to the maximum frequency that is perceived as non-fused tetani by the amputee, which could be as low as 10-20 Hz or as high as 300 Hz (300 impulses per second).
- The stimulation can be provided as a constant-frequency train, as regular bursts of constant frequency stimuli, as random bursts, as

bursts of gradually increasing/decreasing frequency, or in many other patterns that are determined in part by the reported sensations elicited in the amputee and by the expressed preference of the amputee.

5

- The stimulation will preferably be linked to the intensity of a given sensory input that is being monitored by sensors in the prosthetic limb. For example, for single-channel feedback the monitored input could be grip force, or pressure. In such case, the intensity of stimulation of the nerve would be graded, within the available dynamic range, to the range of intensities to be monitored. For example if grip force in the range 0-10 N is to be monitored and the dynamic range of stimulation frequencies detected by the amputee is 0-20 Hz, then the stimulation could be scaled so that every 1 Hz increment represents an increase of 0.5 N and the stimulation frequency range 0-20 Hz represents the grip force range 0-10 N.

For multi-channel systems, use essentially similar patterns but these can be provided independently to each channel, in such a way that all the stimulation parameters may be different and independently controlled for each channel, and each channel can be dedicated to represent a different sensory modality. For example, if four sensory channels are available for feedback from a hand prosthesis, these can be

assigned to represent grip force in the thumb, slip detection in the thumb, angle of the wrist joint, and heat sensed in the palm of the hand. Each of the four sensory inputs would be provided by appropriate sensors built into the prosthetic hand and wrist and would be coded independently as described above for single-channel feedback systems.

Electrical stimulation to provide feedback from a prosthetic limb is delivered preferably by a totally implanted unit that is either battery powered or telemetry-driven and can be externally programmed to optimize stimulation patterns, and its operation can be controlled by the amputee. The sensory information arising from the sensors in the prosthesis is telemetered from a transmitter in the artificial limb to a receiver implanted in the stump. When the prosthetic limb is in use, the sensory feedback system would override and substitute for the background activity from the phantom limb pain treatment stimulator, which would be switched on at other times.

In summary, some major aspects of this invention provide:

1. A method for treating phantom limb pain by providing a flow of sensory traffic to the cortex, arising from the missing limb by way of implanted interfaces to nerves.
2. A method for providing sensory feedback to amputee arising from

sensors in a prosthetic limb by way of implanted interfaces to nerves so as to provide sensory feedback to amputee, useful for controlling a prosthetic limb.

- 5
3. A system for providing sensory feedback to an amputee comprising sensors in a prosthetic limb; implanted interfaces to nerves; and a stimulator for stimulating the nerves by way of the implanted interfaces in response to signals from the sensors.
4. A system for treating phantom limb pain comprising implanted interfaces to nerves; and a stimulator for stimulating the nerves by way of the implanted interfaces to provide a flow of sensory traffic to the amputee's cortex.
5. A system for both treating phantom limb pain and providing sensory feedback to an amputee, the system comprising implanted interfaces to nerves; and a stimulator for stimulating the nerves by way of the implanted interfaces, the stimulator selectively capable of either providing sensory feedback to amputee, useful for controlling a prosthetic limb, by stimulating the nerves by way of the implanted interfaces in response to signals from the sensors or providing a stream of nerve stimulation signals to alleviate phantom limb pain.

- 5
6. Methods and systems as described above wherein the interfaces comprise cuff stimulating electrodes.
 6. Methods and systems as described above wherein the interfaces comprise multi-channel stimulating electrodes.
 7. Methods and systems as described above wherein the interfaces comprise multi-chambered nerve cuff stimulating electrodes.
 8. Systems as described above comprising a telemetry signal receiver located in or near limb stump.
 9. A phantom-limb pain treatment stimulator unit implanted in limb stump or body.
 10. Systems comprising artificial sensors and a transmitter located in a prosthetic limb for transmitting signals to a receiver located to transmit sensory feedback signals to nerves in an amputee.

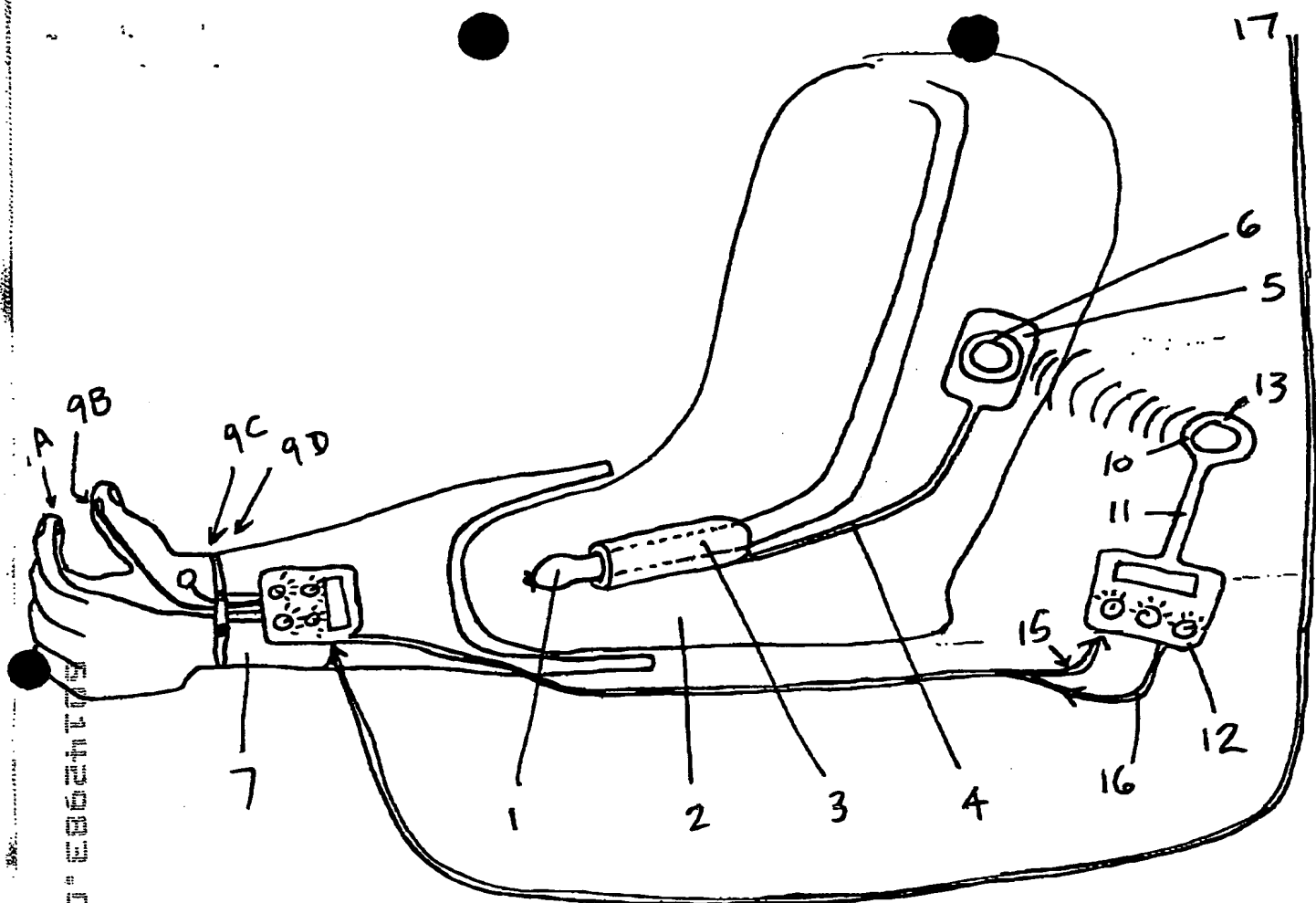


FIG. 1 - Sensory Feedback and
Phantom Limb Control
System - Preferred Embodiment

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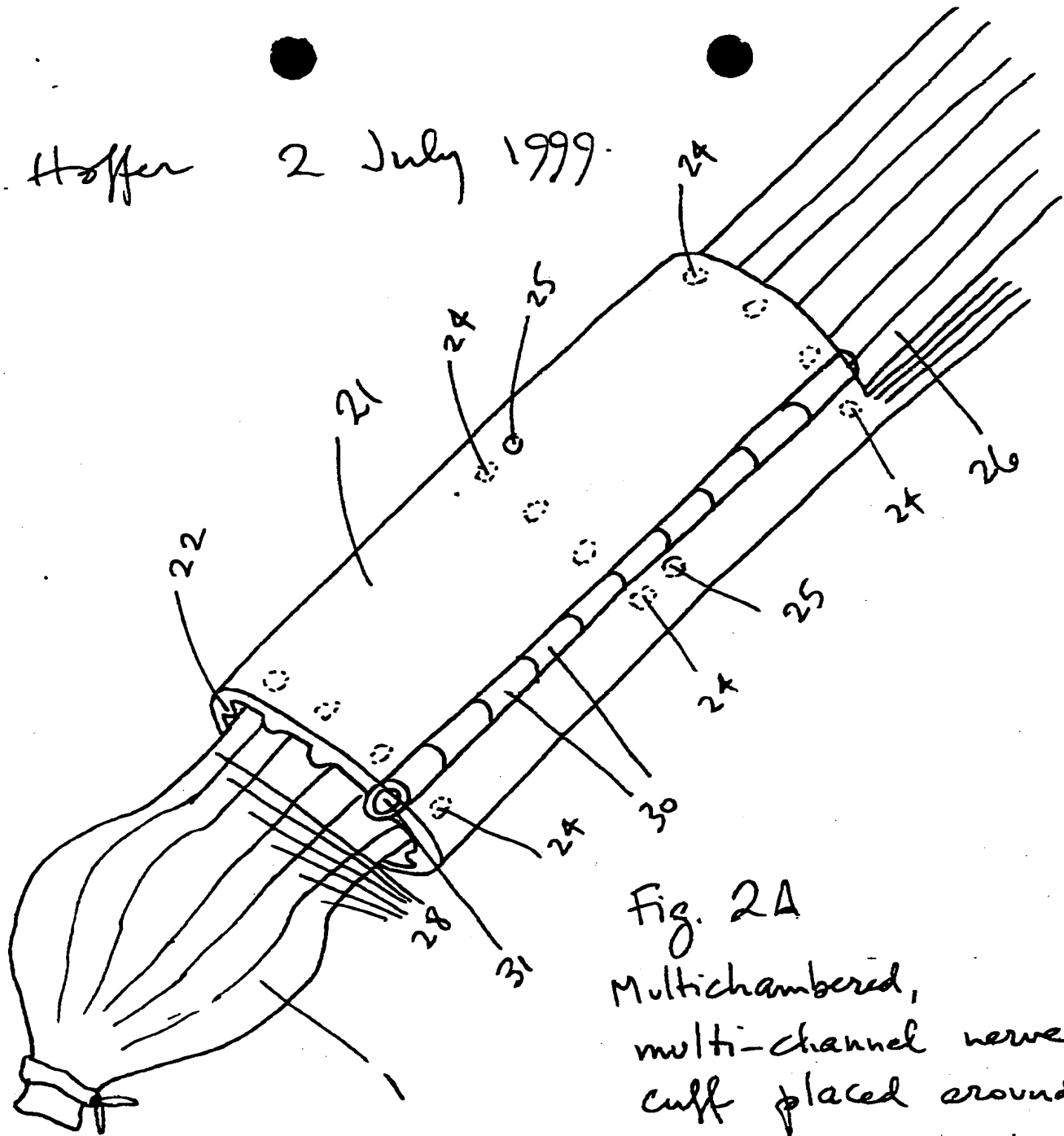
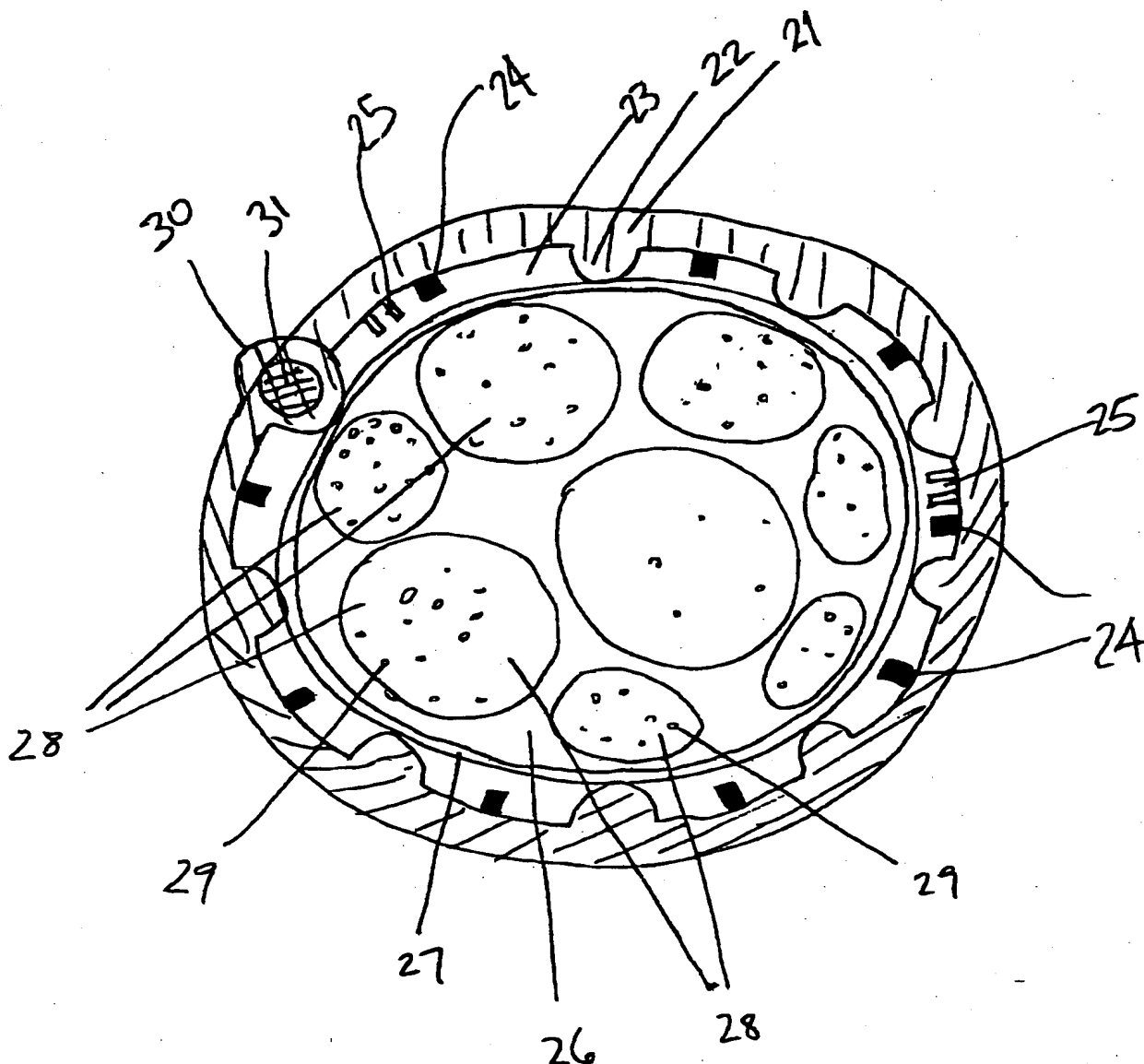


Fig. 2A
Multichambered,
multi-channel nerve
cuff placed around
stump of amputated
nerve to provide
sensory feedback via
electrical stimulation of electrodes inside the cuff

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J.A. Hoffer 2 July 99 Fig. 2B.
Cross-sectional view of a multi-channel,
multichambered nerve cuff placed around
a peripheral nerve inside an amputated limb.

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